



April 3, 2014

## **EDAP Reports Fourth Quarter 2013 and Full Year Results**

### **Highlights**

- Major milestones successfully achieved for Ablatherm-HIFU FDA PMA process
- Strong lithotripsy sales traction in the US with greater than twofold sales increase
- Record sales backlog of lithotripsy and HIFU devices entering 2014

LYON, France, April 3, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the fourth quarter and year ended December 31, 2013, and provided an update on recent strategic developments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "We are pleased with the continued progress that our PMA submission has made over the past year. Just last month, we completed the question and answer phase with the FDA. We are now advancing towards the FDA advisory panel meeting."

Mr. Oczachowski continued, "Our 2013 topline results were in line with the prior year on a constant currency basis and the year-over-year decrease in our total GAAP revenues was primarily due to the significant exchange loss of the Euro compared to the Japanese Yen. We are pleased with the strong traction of our lithotripsy business in the U.S. with a twofold sales increase in 2013. Starting in 2014, we have a record sales backlog with over fifteen lithotripters and five HIFU devices, comprised of two Focal One and three Ablatherms."

### **Fourth Quarter 2013 Results**

Total revenue for the fourth quarter 2013 was EUR 8.1 million (USD 11.0 million). The current quarter revenue compared to EUR 9.4 million (USD 12.3 million) for the fourth quarter 2012 and a 45% sequential increase over EUR 5.6 million (USD 7.4 million) for the third quarter 2013.

Total revenue for the HIFU division was EUR 1.5 million (USD 2.1 million) for the fourth quarter 2013, compared to EUR 2.3 million (USD 3.0 million) for the same period in 2012. Results for the fourth quarter 2013 reflected the sale of one Focal One device, as compared to three HIFU devices sold in the same period last year.

For the three months ended December 31, 2013, total revenue for the Lithotripsy division was EUR 6.6 million (USD 8.9 million), compared to EUR 7.1 million (USD 9.3 million), during the year ago period. During the fourth quarter 2013, the Company recorded sales of eighteen lithotripsy machines, comprised of 13 Sonolith i-move devices and five Sonolith i-sys devices, compared to a total of 21 devices sold in the fourth quarter of 2012.

Gross profit for the fourth quarter 2013 was EUR 3.3 million (USD 4.4 million), compared to EUR 3.9 million (USD 5.1 million) for the year ago period. Gross profit margin was 40.2% in the fourth quarter 2013, compared to 41.3% in the year ago period. The change in the gross profit margin was mostly attributed to the negative currency variations against the Euro.

Operating expenses were EUR 3.0 million (USD 4.1 million) for the fourth quarter 2013, compared to EUR 3.6 million (USD 4.7 million) for the same period 2012. Operating profit was EUR 226,000 (USD 309,000) for the fourth quarter 2013, compared to an operating profit of EUR 254,000 (USD 331,000) in the fourth quarter of 2012.

Net loss for the fourth quarter 2013 was EUR 570,000 (USD 778,000), or EUR 0.03 per diluted share, compared to net loss for the fourth quarter of 2012 of EUR 1.1 million (USD 1.4 million), or EUR 0.06 per diluted share.

### **Full Year 2013 Results**

Total revenue for the full year ended December 31, 2013 was EUR 24.1 million (USD 32.0 million) and EUR 26.0 million on a constant currency basis, compared to EUR 26.1 million (USD 33.6 million) for the full year 2012. 2013 revenue included the sales of 45 lithotripsy devices and three HIFU devices.

Gross profit for the full year 2013 was EUR 9.3 million (USD 12.4 million), compared to EUR 10.4 million (USD 13.5 million) for the full year 2012. Operating loss was EUR 2.8 million (USD 3.7 million), compared to EUR 2.0 million (USD 2.6 million) for the same period 2012.

Net loss for the full year 2013 was EUR 5.0 (USD 6.7 million), or EUR 0.24 per diluted share, compared to a full year 2012 net loss of EUR 7.5 million (USD 9.7 million).

At December 31, 2013, cash and cash equivalents, including short-term treasury investments, were EUR 7.7 million (USD 10.6 million). The Company's net utilization of cash was EUR 396,000 in the fourth quarter 2013 and included the EUR 8.5 million net proceeds from the May 2013 capital increase and the EUR 6.0 million full repayment in June 2013 of the remaining financial debt.

## Conference Call

EDAP will hold a conference call on today, Thursday, April 3, 2014, at 8:30 a.m. EDT to discuss the results. The dial-in numbers are 1-877-300-8521 for domestic callers and 1-412-317-6026 for international callers. The conference ID number for both is 10040166. A live webcast of the conference call will be available online from the investor relations page of the Company's corporate website at [www.edap-tms.com](http://www.edap-tms.com).

After the live event, the webcast will remain available on EDAP's website, [www.edap-tms.com](http://www.edap-tms.com), through May 1, 2014. In addition, a telephonic replay of the call will be available until April 10, 2014. The replay dial-in numbers are 1-877-870-5176 for domestic callers and 1-858-384-5517 for international callers. Please use event passcode 10040166.

## About EDAP TMS SA

EDAP TMS SA markets today Ablatherm<sup>®</sup> for high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option with a low occurrence of side effects. Ablatherm-HIFU is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option, or for patients who failed radiotherapy treatment. Ablatherm-HIFU is approved and commercialized in Europe as a treatment for prostate cancer and is currently under regulatory review in the U.S. following submission of the Pre-Market Approval Application in February 2013 after the completion of a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) granted by the FDA. In February 2013, the Company introduced a new innovative HIFU device, the Focal One<sup>®</sup> dedicated to focal therapy of prostate cancer. Focal One<sup>®</sup> is CE marked but is not FDA approved. The Company also develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment (the Sonolith<sup>®</sup> range) for treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the Company, please visit <http://www.edap-tms.com>, and <http://www.hifu-planet.com>.

## Forward-Looking Statements

In addition to historical information, this press release may contain forward-looking statements. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others the uncertainties of the U.S. FDA approval process, the clinical status and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device. Factors that may cause such a difference also may include, but are not limited to, those described in the Company's filings with the Securities and Exchange Commission and in particular, in the sections "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 20-F. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

### EDAP TMS S.A.

#### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands of Euros and U.S. Dollars, except per share data)

Three Months Ended:		Three Months Ended:	
December 31, 2013	December 31, 2012	December 31, 2013	December 31, 2012

	Euros	Euros	\$US	\$US
Sales of medical equipment	5,552	7,200	7,583	9,397
Net Sales of RPP and Leases	1,033	1,058	1,411	1,380
Sales of spare parts, supplies and Services	1,492	1,121	2,038	1,463
<b>TOTAL NET SALES</b>	<b>8,076</b>	<b>9,378</b>	<b>11,032</b>	<b>12,240</b>
Other revenues	11	45	15	59
<b>TOTAL REVENUES</b>	<b>8,087</b>	<b>9,423</b>	<b>11,046</b>	<b>12,299</b>
Cost of sales	(4,834)	(5,534)	(6,603)	(7,222)
<b>GROSS PROFIT</b>	<b>3,253</b>	<b>3,889</b>	<b>4,443</b>	<b>5,076</b>
Research & development expenses	(570)	(673)	(778)	(878)
S, G & A expenses	(2,457)	(2,963)	(3,356)	(3,867)
Total operating expenses	(3,026)	(3,636)	(4,134)	(4,745)
<b>OPERATING PROFIT (LOSS)</b>	<b>226</b>	<b>254</b>	<b>309</b>	<b>331</b>
Interest (expense) income, net	(662)	(591)	(905)	(772)
Currency exchange gains (loss), net	(88)	(735)	(120)	(959)
Other income (loss), net	(2)	--	(3)	--
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(526)</b>	<b>(1,073)</b>	<b>(719)</b>	<b>(1,400)</b>
Income tax (expense) credit	(44)	(26)	(60)	(34)
<b>NET INCOME (LOSS)</b>	<b>(570)</b>	<b>(1,099)</b>	<b>(778)</b>	<b>(1,434)</b>
Earning per share - Basic	(0.03)	(0.06)	(0.04)	(0.08)
Average number of shares used in computation of EPS	21,789,670	18,372,229	21,789,670	18,372,229
Earning per share - Diluted	(0.03)	(0.06)	(0.04)	(0.08)
Average number of shares used in computation of EPS for positive net income	21,789,670	18,372,229	21,789,670	18,372,229

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2013 average three months noon buying rate of 1 Euro = 1.3659 USD, and 2012 average three months noon buying rate of 1 Euro = 1.3051 USD.

**EDAP TMS S.A.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Twelve Months Ended:		Twelve Months Ended:	
	December 31, 2013 Euros	December 31, 2012 Euros	December 31, 2013 \$US	December 31, 2012 \$US
Sales of medical equipment	14,767	17,009	19,645	21,959
Net Sales of RPP and Leases	3,922	3,988	5,218	5,148
Sales of spare parts, supplies and Services	5,375	5,021	7,151	6,482
<b>TOTAL NET SALES</b>	<b>24,065</b>	<b>26,018</b>	<b>32,014</b>	<b>33,589</b>
Other revenues	15	47	20	61
<b>TOTAL REVENUES</b>	<b>24,080</b>	<b>26,065</b>	<b>32,034</b>	<b>33,650</b>
Cost of sales	(14,761)	(15,632)	(19,636)	(20,181)

<b>GROSS PROFIT</b>	<b>9,319</b>	<b>10,433</b>	<b>12,397</b>	<b>13,469</b>
Research & development expenses	(2,595)	(2,659)	(3,452)	(3,432)
S, G & A expenses	(9,479)	(9,805)	(12,610)	(12,658)
Total operating expenses	<u>(12,074)</u>	<u>(12,463)</u>	<u>(16,062)</u>	<u>(16,090)</u>
<b>OPERATING PROFIT (LOSS)</b>	<b>(2,755)</b>	<b>(2,030)</b>	<b>(3,665)</b>	<b>(2,621)</b>
Interest (expense) income, net	(901)	(4,594)	(1,198)	(5,931)
Currency exchange gains (loss), net	(1,230)	(733)	(1,636)	(947)
Other income (loss), net	<u>--</u>	<u>--</u>	<u>(1)</u>	<u>--</u>
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(4,886)</b>	<b>(7,358)</b>	<b>(6,500)</b>	<b>(9,499)</b>
Income tax (expense) credit	<u>(135)</u>	<u>(118)</u>	<u>(179)</u>	<u>(152)</u>
<b>NET INCOME (LOSS)</b>	<b><u>(5,021)</u></b>	<b><u>(7,475)</u></b>	<b><u>(6,680)</u></b>	<b><u>(9,651)</u></b>
Earning per share - Basic	(0.24)	(0.43)	(0.32)	(0.55)
Average number of shares used in computation of EPS	20,593,720	17,556,395	20,593,720	17,556,395
Earning per share - Diluted	(0.24)	(0.43)	(0.32)	(0.55)
Average number of shares used in computation of EPS for positive net income	20,593,720	17,556,395	20,593,720	17,556,395

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2013 average twelve months noon buying rate of 1 Euro = 1.3303 USD, and 2012 average twelve months noon buying rate of 1 Euro = 1.2910 USD.

**EDAP TMS S.A.**  
**CONSOLIDATED BALANCE SHEETS HIGHLIGHTS**  
**(Amounts in thousands of Euros and U.S. Dollars)**

	<b>Dec. 31,</b>	<b>Sept. 30,</b>	<b>Dec. 31,</b>	<b>Sept. 30,</b>
	<b>2013</b>	<b>2013</b>	<b>2013</b>	<b>2013</b>
	<b>Euros</b>	<b>Euros</b>	<b>\$US</b>	<b>\$US</b>
Cash, cash equivalents and short term investments	7,681	6,439	10,584	8,716
Total current assets	22,171	20,873	30,551	28,252
Total current liabilities	11,589	10,596	15,969	14,342
Shareholders' Equity	9,284	10,011	12,794	13,550

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.3780 USD, on December 31, 2013 and at the noon buying rate of 1 Euro = 1.3535 USD, on September 30, 2013.

**EDAP TMS S.A.**  
**CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**TWELVE MONTHS ENDED DECEMBER 31, 2013**  
**(Amounts in thousands of Euros)**

HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation
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Sales of goods	1,747	13,020			14,767
Sales of RPPs & Leases	2,335	1,588			3,922
Sales of spare parts & services	<u>1,031</u>	<u>4,344</u>	<u>          </u>	<u>          </u>	<u>5,375</u>
<b>TOTAL NET SALES</b>	<b><u>5,113</u></b>	<b><u>18,952</u></b>	<u>          </u>	<u>          </u>	<b><u>24,065</u></b>
Other revenues	<u>15</u>	<u>--</u>	<u>          </u>	<u>          </u>	<u>15</u>
<b>TOTAL REVENUES</b>	<b><u>5,128</u></b>	<b><u>18,952</u></b>	<u>          </u>	<u>          </u>	<b><u>24,080</u></b>
<b>GROSS PROFIT</b>	<b>2,638 51%</b>	<b>6,681 35%</b>			<b>9,319 39%</b>
Research & Development	(1,097)	(525)	(973)		(2,595)
Total SG&A plus depreciation	<u>(2,244)</u>	<u>(5,655)</u>	<u>(165)</u>	<u>(1,415)</u>	<u>(9,479)</u>
<b>OPERATING PROFIT (LOSS)</b>	<b>(704)</b>	<b>502</b>	<b>(1,138)</b>	<b>(1,415)</b>	<b>(2,755)</b>

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